UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

BARBARA KAISER and ANTON KAISER, Plaintiffs, v. JOHNSON & JOHNSON and ETHICON, INC., Defendants.	)	No. 2:17-cv-00114-PPS-JEM

OPINION AND ORDER

This is a products liability case where Barbara Kaiser claimed to have been substantially and permanently injured by a mesh product that was implanted in her vagina to treat her pelvic organ prolapse. The mesh product was designed and manufactured by defendants Johnson & Johnson and Ethicon, Inc. After a two week trial, the jury agreed with Mrs. Kaiser and found in her favor on her failure to warn and design defect claims. The jury awarded Mrs. Kaiser $10 million in compensatory damages and $25 million in punitive damages. The jury found in the defendants' favor on the claim of loss of consortium brought by Anton Kaiser, Mrs. Kaiser's husband.

Defendants have filed a motion contesting the verdict, seeking judgment as a matter of law on both the failure to warn and design defect claims, or in the alternative a new trial, or in the alternative to that, a remittitur of the jury's damages award. [DE 416.] Because there was sufficient evidence for a reasonable jury to find in favor of Mrs. Kaiser, I will deny defendants' motion for a judgment as matter of law and likewise

deny defendants' motion for a new trial. Similarly, because I find the jury's compensatory damages award was neither monstrously excessive nor the product of passion or prejudice, I will deny Ethicon's request for a remittitur of the jury's compensatory damages award.

The jury's punitive damage award, however, is another story. I find the punitive damages award excessive and unreasonable under controlling law. As such, I will grant defendants' motion for remittitur of the jury's $25 million punitive damage award.

Background

Defendants Ethicon and Johnson & Johnson are corporations which, among other lines of business, design, market, and sell medical devices. Ethicon is a wholly owned subsidiary of Johnson & Johnson. For ease of reference I will refer to both defendants as "Ethicon." One of the devices sold by Ethicon was the Prolift Pelvic Floor Repair System. Prolift is a vaginal mesh which was implanted in Mrs. Kaiser's pelvis in January 2009 to treat her pelvic organ prolapse condition. Mrs. Kaiser subsequently experienced various issues including vaginal pain, pelvic pain, pain during intercourse, bladder spasms, and bowel issues. All of these problems associated with the mesh necessitated a second surgical procedure to have the mesh removed from Mrs. Kaiser's vagina, or at least as much of it as could be removed. There was evidence that once the mesh is implanted it becomes very difficult, if not impossible, to have it all removed; it grows into the tissue, hardens and causes substantial pain.

Mrs. Kaiser alleged in her complaint that her injuries were the result of Prolift's

defective design and that Ethicon did not adequately warn Mrs. Kaiser's surgeon (Dr. Bales) of the risks associated with Prolift. The case was originally filed in the United States District Court for the Southern District of West Virginia, where a consolidated Multi-District Litigation related to Prolift and other vaginal mesh products is pending. [DE 1.] On March 28, 2017 the case was transferred here because all pretrial proceedings had concluded, and the case was ready for trial. [DE 160.]

A jury trial began on February 26, 2018 and each side put on extensive evidence, including multiple witnesses, both fact and expert, both live and through videotaped deposition testimony. Trial concluded on March 8, 2018 and after several hours of deliberations, the jury returned a verdict in favor of Mrs. Kaiser, awarding her $10 million in compensatory damages and $25 million in punitive damages. [DE 405.] Ethicon timely filed the present motion seeking judgment as a matter of law, or in the alternative a new trial, or in the alternative of that, a remittitur of the jury's damages awards.

Legal Standard

It is important to note at the outset the posture and standard applicable to defendants' motions. Federal Rule of Civil Procedure 50 governs motions for judgments as a matter of law. Defendants are entitled to a judgment as a matter of law only if I find "that a reasonable jury would not have a legally sufficient evidentiary basis to find" in favor of Mrs. Kaisser. Fed. R. Civ. P. 50(a)(1). In making this determination, I do not approach the case with new eyes, examining the evidence and the jury's verdict as

though I am the fact finder receiving the evidence for the first time. Instead, I may only disregard the jury's verdict "if no reasonable jury could have found in [Mrs. Kaiser's] favor." *Erickson v. Wisc. Dept. of Corrections*, 469 F.3d 600, 601, (7th Cir. 2006). "This is obviously a difficult standard to meet." *Waite v. Bd. of Trustees of Ill. Cmty. Coll. Dist. No. 508*, 408 F.3d 339, 343 (7th Cir. 2005). What makes it such a daunting standard is that the Supreme Court has instructed that I "must disregard all evidence favorable to the moving party that the jury is not required to believe." *Reeves v. Sanderson Plumbing Prod., Inc.*, 530 U.S. 133, 150–51 (2000).

In considering the present motion for judgment as a matter of law, it is not my role to "re-weigh the evidence presented at trial or make credibility determinations." *Black & Decker Inc. v. Robert Bosch Tool Corp.*, No. 04 C 7955, 2007 WL 108412, at *1 (N.D. Ill. Jan. 12, 2007) (citation omitted). As the Supreme Court has succinctly put it, "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he is ruling on a motion for summary judgment or for a directed verdict." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 255 (1986).

The standard applicable to Ethicon's motion for a new trial is similar but distinct. Federal Rule of Civil Procedure 59(a) governs a motion for a new trial and states that a new trial may be granted "for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. Proc. 59(a)(1)(A). The Seventh Circuit has explained, "'[a] motion for a new trial should succeed 'only if the verdict is

against the manifest weight of the evidence.'" *ABM Marking, Inc. v. Zanasi Fratelli, S.R.L.*, 353 F.3d 541, 545 (7th Cir. 2003) (quoting *Lowe v. Consol. Freightways of Del., Inc.*, 177 F.3d 640, 641 (7th Cir. 1999); *Latino v. Kaizer*, 58 F.3d 310, 315 (7th Cir. 1995) ("[N]ew trials granted because the verdict is against the weight of the evidence are proper only when the record shows that the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be overturned or shocks our conscience."). Defendants "must demonstrate that no rational jury could have rendered a verdict against them." *King v. Harrington*, 447 F.3d 531, 534 (7th Cir. 2006) (citation omitted).

Once again, in making this determination, I "must view the evidence in a light most favorable to [Mrs. Kaiser], leaving issues of credibility and weight of evidence to the jury." *Id.* "[I]t is an invasion of the jury's province to grant a new trial merely because the evidence was sharply in conflict." *Latino*, 58 F.3d at 315. "Even when evidence is contradictory, '[i]t's the jury's job—not the district court's job or the job of a panel of appellate judges—to figure out who's telling the truth.'" *United States v. Hassebrock,* 663 F.3d 906, 920 (7th Cir. 2011) (citation omitted).

Discussion

This was a close case with conflicting expert testimony. On the one hand, it is certainly true that defendants put forth evidence which supported their theory of the case: that Prolift was a safe product, that all necessary warnings were fully disclosed to the necessary individuals, and that Mrs. Kaiser's injuries could not be traced to any harm caused by the vaginal mesh. But it is equally clear the jury did not believe or find

defendants' evidence persuasive enough to render a verdict in their favor. On the contrary, the jury obviously believed Mrs. Kaiser and the witnesses who testified that Prolift was a defective product, that Ethicon knew of the risks associated with Prolift but chose not to disclose them to surgeons using the product, and that Mrs. Kaiser's injuries were the result of her having Prolift surgically implanted in her. Given the substantial evidence on both sides of the ledger, it was up to the jury to decide whose story was more believable. With these general thoughts in mind, I will now turn to the various motions brought by Ethicon.

A. Judgment as a Matter of Law as to Failure to Warn

Defendants' central argument concerning why Mrs. Kaiser's failure to warn claim must fail is one of causation. Ethicon argues that Kaiser failed to offer sufficient evidence at trial that Dr. Bales, the surgeon who implanted the Prolift device into her, was not adequately warned of risks related to Prolift. [DE 416 at 10-16.] It is the sufficiency of the warnings to Dr. Bales — not Mrs. Kaiser — that is at issue here. This is because under the so-called "sophisticated or learned intermediary doctrine" warnings for prescription drugs and medical devices "need only be directed to doctors, not patients who are the ultimate users." *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 549 (Ind. Ct. App. 1979). Typically, this is a question of fact for the jury to determine because "the intermediary's alleged sophistication may be more or less reasonable given the product's nature, complexity and associated dangers, the likelihood that the intermediary will communicate warnings to the ultimate consumer, the dangers posed

to the ultimate consumer by an inadequate or nonexistent warning, and the feasibility of requiring the manufacturer to directly warn the product's ultimate consumers." *Nat. Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 164 (Ind. Ct. App. 1997).

In support of their argument, defendants rely primarily upon Dr. Bales's testimony. But Dr. Bales' testimony was in flux; he said different things at different times in his deposition. It's worth pointing out that Dr. Bales was not subpoenaed to testify at the trial despite the fact that he was within the subpoena power of the Court. I found this curious, but both parties chose instead to simply rely on his deposition testimony, a portion of which was read to the jury. It is true, as the defendants correctly note, that Dr. Bales's testimony was not entirely favorable to Mrs. Kaiser. For example, he testified that he did not read the Instructions for Use ("IFU") before every surgery. [DE 395, Ex. H, Bales Tr. at 116:19-118:1.] But Dr. Bales also testified that he read the IFU for Prolift multiple times, followed it when implanting Prolift, and that the IFU influenced his decision to implant Prolift in Mrs. Kaiser. [*Id.* at 19:05-19:21; *id.* at 19:23-20:09.]

On the issue of whether he would have done anything differently had he known at the time of Mrs. Kaiser's surgery what he later found out, Dr. Bales' testimony waxed and waned. On the one hand, when asked generally if he "would have done anything differently with respect to Ms. Kaiser's . . . surgery" he responded, "No, not looking back, I don't think I would have done anything differently." [*Id.* at 84:9-1, 85:6-10.] On the other hand Dr. Bales specifically testified that once he realized that the

complications from Prolift were happening a "little too frequently" and the "risks started to become a little more than you would like and the benefits are not abundantly clear," he started recommending against the continued use of vaginal mesh. [*Id.* at 51:15-52:6.] It was in this context that Dr. Bales provided the following critical piece of testimony: he concluded that it was "fair to say that in hindsight, had I seen potential problems that occurred, I may not have started employing the Prolift." [*Id.* at 22:16-23.] This was the clinching testimony relating to causation that allowed the failure to warn claim to go to the jury. So while Dr. Bales said some things that were contradictory, it was ultimately for the jury to evaluate his testimony and decide what weight, if any, to put on any particular piece of evidence.

In sum, there was evidence showing that Dr. Bales read and reviewed the Prolift IFU many times prior to Mrs. Kaiser's surgery. There was also evidence that Dr. Bales was familiar with some of the risks associated with Prolift prior to Mrs. Kaiser's surgery, but not all of them. In that regard, the most damning testimony from Dr. Bales was his statement that if he knew at the time of Mrs. Kaiser's surgery what he later found out about the problems associated with Prolift, he would not have used the device. In other words, after learning more about the Prolift after implanting it in Mrs. Kaiser, he began to have doubts concerning the efficacy of the product compared to its risks. This was compelling testimony from an experienced surgeon that the jury was entitled to credit.

Defendants likewise argue that Prolift's warnings were sufficient as a matter of law because risks associated with Prolift were fully disclosed in literature and commonly known to pelvic floor surgeons like Dr. Bales. [DE 416 at 11-12.] But Dr. Bales and Kaiser's expert Dr. Elliott testified to the contrary — that they were not aware of every risk claimed in January 2009 or that such risks were necessarily generally known amongst pelvic floor surgeons. [DE 395, Ex. H, Bales Tr. at 22:16-19; Trial Tr. 610:3-15 (testimony of Dr. Elliott).] The jury heard testimony from Dr. Elliott that the frequency, severity and permanence of certain complications were not disclosed within the IFU. [Trial Tr. at 398:4-399:6; *id.* at 388:7-390:19.] It was the role of the jury, as the fact finder, to determine whether the warning was adequate under the sophisticated intermediary doctrine. *Downs*, 685 N.E.2d at 163 ("Whether a manufacturer has discharged its duty under the sophisticated intermediary doctrine is almost always a question for the trier of fact."). And the jury decided that the warning was inadequate in this case.

Defendants further criticize the testimony of Mrs. Kaiser's experts, Dr. Elliott and Dr. Rozenzweig, for testifying that they expect all risks related to a medical device to be disclosed within the IFU. [DE 416 at 11.] Defendants argue that this testimony put forth an impermissibly high standard— higher than what is required under the law. But defendants' arguments suffer from a fatal flaw; plaintiffs' experts did not testify as to the legal standard applicable to a failure to warn or opine on the law. The jury instructions stated the correct legal standard, namely that a manufacturer need only

disclose "reasonable warnings about the dangers of the product when the seller, by exercising reasonable diligence, could have made those warnings available to the user or consumer." [Trial Tr. 1744:15-19.] There is no reason to believe that the jury disregarded those instructions in reaching its verdict. *See Schandelmeier-Bartels v. Chicago Park Dist.,* 634 F.3d 372, 387 (7th Cir. 2011) ("We assume that the jury followed the instructions as they were provided.").

In sum, there was sufficient evidence for a reasonable jury to conclude that Ethicon failed to warn Dr. Bales of the necessary risks related to Prolift. The law does not require a plaintiff to offer unequivocal evidence at a trial or proof beyond a reasonable doubt, only sufficient evidence that a reasonable jury could find in its favor. *See* Fed. R. Civ. P. 50(a)(1). For the reasons I have just stated, Mrs. Kaiser met that standard here on the failure to warn claim.

B. Judgment as a Matter of Law as to Design Defect

On the design defect claim, defendants raise four arguments as to why they are entitled to a judgment as a matter of law: First, that they were entitled to a state of the art presumption under Indiana law; second, that the evidence offered by Kaiser failed to establish that Prolift was in fact defective; third, that Kaiser failed to establish that her injuries were caused by Prolift; and fourth, for the first time before me, Ethicon raises a conflict preemption defense, arguing that the FDA's requirements that new or altered products receive some form of FDA clearance before they can be marketed conflicts with Mrs. Kaiser's state law claim. I am not persuaded by any of these arguments.

1. State of the Art Presumption under Indiana Law

The Indiana Products Liability Act (IPLA) allows for a defendant to avail itself of a rebuttal presumption that its product was not defective if it was designed and manufactured "in conformity with the generally recognized state of the art applicable to the safety of the product at the time the produce was designed, manufactured, packaged, and labeled." Ind. Code § 34-20-5-1. The statute does not define "state of the art" but courts have defined it to mean "the best technology reasonably feasible." *Indianapolis Athletic Club, Inc. v. Alco Standard Corp.*, 709 N.E.2d 1070, 1074 (Ind. Ct. App. 1999). In order to avail itself of the presumption, a defendant must put forth "[e]vidence of the existing level of technology, industry standards, the lack of other advanced technology, the product's safety record, [or] the lack of prior accidents . . . in order to prove that a product is state of the art." *Wade v. Terex-Telelect, Inc.* 966 N.E.2d 186, 192 (Ind. Ct. App. 2012) (citing *Weller v. Mack Trucks, Inc.*, 570 N.E.2d 1341, 1343 (Ind. Ct. App. 1991). A defendant must make a showing that no other similarly advanced technology existed at the time the product was designed and manufactured. *Wade*, 966 N.E.2d at 193-194.

On this issue, this case is similar, albeit the inverse, to the facts before the Indiana Court of Appeals in *Wade*. In that case, the trial court actually gave the "state of the art" jury instruction but the Court of Appeals found that to be improper and reversible error because the defendants failed to offer sufficient evidence at trial which would meet their burden to make use of the rebuttable presumption. The court in *Wade* held that the

defendant was not entitled to the rebuttable presumption in part because they manufactured products which both had and did not have the design defect in question (a lack of interior step in a "bucket" attached to a vehicle used by electrical workers to repair power lines). *Wade*, 966 N.E.2d at 194-195 ("The fact that Terez manufactured a liner with an interior step at the time that the liner at issue was manufactured shows that there was other advanced technology available.").

I was guided by *Wade* in my decision not to give a state the art instruction. At the time Prolift was launched, defendants manufactured another vaginal mesh material, known as Ultrapro. This existence of an alternative belies any notion that Prolift was truly ***the*** state of the art at the time. It is true that certain witnesses did testify that Prolift was in their opinion a good product and "better than anything that has been out there before." [DE 387 Hinoul Tr. 1282:22-1283:1.] But there was competing testimony that even at the time Prolift was launched, it was contemplated that the mesh material used in Prolift would be replaced, and potentially by Ultrapro, another mesh product produced by Ethicon. [DE 395, Ex. E, Hinoul Tr. 891:2-892:3; DE 395, Ex. I, Arnaud Tr. 367:7-368:5.]

Likewise, there was evidence that at the time Prolift first began to be marketed, defendants had not conducted any clinical trials of Prolift in humans. [DE 395, Ex. E, Hinoul Tr. 200:9-200:12; *id.* at 726:21-726:25; *id.* at 727:1-727:4.] Thus, there was no evidence which Ethicon did or could have introduced showing Prolift's specific safety track record at the time it was brought to market. *See Wade*, 966 N.E.2d at 194 ("Terex

introduced no evidence regarding the product's safety record and the lack of prior accidents pertaining to the buckets . . ."). Given that defendants did not present sufficient evidence to warrant the rebuttal presumption and jury instruction on state of the art, they cannot sufficiently show that they were entitled to judgment as a matter of law on this same issue.

2. Lack of Design Defect

Defendants next argue that all of Mrs. Kaiser's complications "were well known to pelvic floor surgeons, including Dr. Bales." [DE 416 at 19.] Without any unknown or undisclosed risk, a product cannot have been unreasonably dangerous. *Id.* But as I did above, I must reject this argument relating to Dr. Bale's knowledge because, while there was testimony indicating that Dr. Bales appreciated many risks associated with Prolift, there was additional testimony, both from Dr. Bales himself and Dr. Elliott that both he and the pelvic floor surgeon community were not fully apprised of every risk associated with Prolift. [DE 395, Ex. H, Bales Tr. at 22:16-19; Trial Tr. 610:3-15.] Thus it was not unreasonable as a matter of law for the jury to find for Kaiser on this element of her claim.

Defendants' main argument on this element, however, is that I reconsider my prior ruling on whether proof of a safer alternative design is an element of a design defect claim under Indiana law. [DE 416 at 19-20.] My prior ruling [DE 329 at 6-14], that such proof is not an element of a design defect claim under Indiana law, was dictated by the Indiana Supreme Court's decision in *TRW Vehicle Safety Systems, Inc. v. Moore*,

936 N.E.2d 201 (Ind. 2010). In *TRW*, the Indiana Supreme Court squarely rejected any such requirement based upon the language of the IPLA. *TRW*, 936 N.E.2d at 209 ("Thus the statute itself prescribes the applicable standard of care. We decline to require proof of any additional or more particular standard of care in product liability actions alleging a design defect."); *id.* at 209, n.2 (noting that Indiana legislature declined to adopt the America Law Institute's "different approach" which requires proof of safer alternative design as an element of a design defects claim). Notwithstanding some loose language in several cases to the contrary, it remains my view the *TRW* settles the issue of whether evidence of a safer alternative design is necessary in a design defect case brought under Indiana. The Indiana Supreme Court has stated explicitly that such proof is not required. That's the end of the matter from my point of view.

What's more, defendants have not offered any additional basis for me to reconsider my ruling but instead state that they have done so only "to preserve the issue" while repeating their prior arguments. [DE 416 at 19.] Nor have they provided any persuasive reason as to why I should depart from Indiana law as decided by Indiana's highest court. Since this issue was squarely decided in *TRW* and there has been no intervening change in the law or other manifest error, I decline to reconsider this issue or find it a basis for a judgment as a matter of law in defendants' favor. *Cain v. Grams*, No. 09-CV-145-BBC, 2009 WL 2408342, at *1 (W.D. Wis. July 31, 2009) ("[A] motion to reconsider should not be used to rehash previous arguments.") (citing *Oto v. Metro Life Insurance Co.,* 224 F.3d 601, 606 (7th Cir. 2000)); *Lock Realty Corp. IX v. U.S.*

Health, LP, No. 3:06-CV-487RM, 2010 WL 148296, at *1 (N.D. Ind. Jan. 13, 2010) ("[T]he court's orders are not mere first drafts, subject to revision and reconsideration at a litigant's pleasure.").

3. Causation

Ethicon next argues that Mrs. Kaiser failed to offer sufficient evidence that Prolift was the actual cause of her injuries. On this argument, defendants seem to misunderstand what was required, arguing that Kaiser "failed to ***rule out*** other plausible causes" or that Kaiser's "treating physicians could not say ***with certainty*** that mesh was the cause of her pain." [DE 416 at 20 (emphasis added).] Kaiser's burden as to causation is not one of absolute certainty or to prove that Prolift was the sole cause of her injuries. *Smith v. Beaty*, 639 N.E.2d 1029, 1034 (Ind. Ct. App. 1994) ("The defendant's act need not be the sole cause of the plaintiff's injuries."); *Lapsley v. Xtek, Inc.,* 689 F.3d 802, 814 (7th Cir. 2012) ("Indiana design defect law does not require absolute certainty on every aspect of causation[.]"). Instead, Kaiser was required to put forth sufficient evidence that a reasonable jury could find in her favor that Prolift caused her injuries.

She did that. Dr. Rosenzweig testified as to specific defects he found with Prolift which lead it to "band, contract, deform, rope, [and] curl" which then caused Kaiser's injuries, including pelvic pain and pain with sexual intercourse. [Trial Tr. 658:13-6:59:7.] Likewise, Dr. Johnson, who removed Mrs. Kaiser's vaginal mesh, testified that the Prolift mesh, along with scar tissue, was the likely cause of Kaiser's pelvic pain and pain associated with sexual intercourse. [DE 395, Ex. D, Dr. Johnson Tr. 48:8-49:25.] The jury

was entitled to, and apparently did, believe these statements by plaintiffs' medical experts and witnesses. This was not unreasonable and therefore the jury's verdict may not be aside on this basis.

4. Conflict Preemption

Ethicon argues that because FDA regulations "unequivocally require a manufacture to submit a new Section 510(k) premarket notification before marketing" a new or changed device, they cannot be held liable under state tort law for any supposed design defect of Prolift. [DE 416 at 22; *see also* 21 C.F.R. § 807.81(a)(3) (listing when premarket approval for medical devices is required).] This argument, which defendants unsuccessfully raised before the MDL court but never previously before me, *see Mullins v. Ethicon, Inc.*, 147 F. Supp.3d 478 (S.D.W. Va. 2015), does not persuade me that defendants are entitled to judgment as a matter of law.

Preemption is a legal doctrine rooted in the Constitution's Supremacy Clause, namely that Congress may preempt or invalidate state laws through federal legislation. *Oneok, Inc. v. Learjet, Inc.,* 135 S. Ct. 1591, 1595 (2015). Preemption can be express or implied. There are two kinds of implied preemption, one known as field preemption (not at issue here) and another, known as conflict preemption. *Id.* Conflict preemption occurs where "compliance with both state and federal law is impossible" or a state's law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (quoting *California v. ARC America Corp.*, 490 U.S. 93, 100 (1989)). If this occurs, state law must give way; it is preempted by the federal law.

The Supreme Court has enunciated two guiding principles on this issue. First, I must begin with a presumption against preemption because "courts should assume that the historic police powers of the States are not superseded unless that was the clear and manifest purpose of Congress." *Arizona v. United States*, 132 S. Ct. 2492, 2501 (2012) (citation and internal quotation marks omitted). Second, I must focus on Congressional intent and purpose, examining "the text and structure of the statute at issue." *CXZ Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993). Bearing these in mind, it is clear that Congress has not intended or evidenced a purpose to abrogate state product liability claims for design defects through the 510(k) process for medical devices.

Section 510(k) review was created by Congress through the passage of legislation called the Medical Device Amendments of 1976 as an exception to the FDA's more rigorous premarket approval process. The intention of this exception was to avoid allowing existing manufacturers to have a temporary monopoly within a medical device market while new products were subject generally to the premarket approval process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). In *Lohr*, the Court explicitly stated that Congress did not intend to preempt the traditional state law regime of design defect liability through the Section 510(k) process. "There is no suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. That status quo

included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design." *Lohr*, 518 U.S. at 494.

Ethicon tries to argue around this facially dispositive language in *Lohr* by pointing me towards more recent Supreme Court precedent, which has held state tort law claims preempted in the context of generic pharmaceutical labeling. *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472 (2013). But Ethicon's reliance on these generic drug labeling cases is inapposite because in those cases, the Court focused and primarily based its holdings on the fact that federal law mandates generic drugs maintain the same label as the brand name equivalent. *PLIVA*, 564 U.S. at 620 ("Federal law does not dictate the text of each generic drug's label, but rather ties those labels to their brand-name counterparts."). This distinction matters. Federal law specifically mandates the contents of the labels on generic drugs, and a generic drug manufacturer cannot get around these requirements and thus, any state product liability law attempting to require otherwise is preempted. *See Bartlett*, 570 U.S. at 486 ("[F]ederal law prevents generic drug manufacturers from changing their labels."). There is no similar Congressional mandate in the field of medical devices like Prolift.

Taken to its logical conclusion, Ethicon's argument would effectively exempt all medical devices from state design defect liability if the safer alternative design was not already pre-cleared by the FDA, under the Section 510(k) or another regulatory scheme. As the MDL court which addressed this issue before me said, this would "destroy state

tort liability for any product subject to even the least rigorous federal regulatory scheme." *Mullins*, 147 F. Supp. 3d at 481. Absent controlling precedent extending *PLIVA* and *Bartlett* beyond the confines of generic drug labeling, I cannot find that medical device manufacturers like Ethicon are immune from state tort liability simply because their product is subject to some federal regulatory oversight. This is especially true given that the Supreme Court made clear in *Lohr* that the Section 510(k) regime for medical devices is decidedly not an issue of safety and that "[t]here is no suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo . . . [including] state-law claims of negligent design." *Lohr*, 518 U.S. at 494.

C. Defendants' Motion for a New Trial

Having found all of defendants' arguments in favor of a judgment as a matter of law unpersuasive, defendants ask in the alternative that I grant them a new trial. First, defendants claim that a new trial is warranted because the jury's verdict was against the weight of evidence and because I refused to instruct the jury as to the state of the art presumption. As discussed above, neither of these arguments were persuasive as to Ethicon's motion for a judgment as a matter of law. Given that the applicable standards are nearly the same, I find them unpersuasive here as well for all of the same reasons. *Compare Erickson*, 469 F.3d at 601 (judgment as a matter of law may be granted only "if no reasonable jury could have found" in nonmoving party's favor) *with*, *King*, 447 F.3d

at 534 (new trial may be granted only when moving party has "demonstrate[d] that no rational jury could have rendered a verdict against them").

Before continuing, however, I must make a further observation concerning Ethicon's motion for a new trial. In order to repackage these arguments in support of a new trial, Ethicon cites to a footnote within the Supreme Court's decision in *Tibbs v. Florida*, 457 U.S. 38, n. 11 (1982) for the proposition that I need not defer to the jury or view evidence in a light favorable to Kaiser. Instead, Ethicon states that I may substitute my views for those of the jury and "may weigh the evidence and in so doing evaluate for [myself] the credibility of the witnesses" in determining whether to grant a new trial. [DE 416 at 20.] This is an incorrect statement of law. *Tibbs* was a case concerning whether the Double Jeopardy clause prohibits a state from retrying a criminal defendant who has his conviction set aside by a state appellate court based upon "the weight of the evidence." It does not speak to the standard on a motion for a new trial under Federal Rule of Civil Procedure 59. Instead, I may only weigh evidence "to determine if it's against the *manifest* weight of evidence." *Whitehead v. Bond*, 680 F.3d 919, 928 (7th Cir. 2012) (italics in original). "The district court, however, cannot grant a new trial just because it believes the jury got it wrong." *Id.* (citation omitted).

D. Defendants' Motion for a New Trial Based Upon Evidentiary Rulings and Jury Instructions

Defendants further argue they are entitled to a new trial based upon various evidentiary rulings and the instructions given to the jury. In reviewing these claims now after the fact, I "must be guided by the principle that 'civil litigants are entitled to a fair trial, not a perfect one'; the Court should decline to order a new trial 'unless there was an error that caused some prejudice to the substantial rights of the parties.'" *Hardy v. City of Milwaukee*, 88 F. Supp. 3d 852, 861 (E.D. Wis. 2015) (quoting *Lemons v. Skidmore,* 985 F.2d 354, 357 (7th Cir. 1993)). Each argument is addressed in turn, but none warrant a new trial whether on their own or collectively. *See Frymire-Brinati v. KPMG Peat Marwick*, 2 F.3d 183, 188 (7th Cir. 1993) (holding that clearly erroneous evidentiary rulings during trial were so numerous that a new trial was necessary).

1. Exclusion of FDA-related Evidence

At trial, Ethicon was precluded from introducing evidence relating to the FDA's premarket clearance process for medical devices, known as Section 510(k) review. They now say that was an error. But Ethicon's motion is simply a rehash of many of the same arguments I previously rejected. [DE 407.] And none of these arguments lead me to believe that my prior ruling was in error.

Ethicon does raise one new argument, premised on a recent ruling from another court: *In re Bard IVC Filters Prods. Liab. Litig.*, 289 F. Supp. 3d 1045 (D. Ariz. 2018). Of course, a district court opinion is not binding precedent. And that is especially so when the opinion concerns an entirely different product (inferior vena cava filters), in a

lawsuit under a different state's (Georgia) law. But I will nonetheless explain why I don't think the analysis in *Bard* is applicable to this case.

In *Bard*, the court allowed, over plaintiffs' objections, for Section 510(k) evidence to be admitted. The court found that compliance with the Section 510(k) process was relevant to whether the manufacturer acted reasonably under Georgia law and the risk-utility test that is used there. The court further found that "any potential confusion can be cured, if necessary, by a limiting instruction regarding the nature of the 510(k) process." *Bard*, 289 F. Supp.3d at 1049. Essentially, the ruling was based on Federal Rule of Evidence 403 and the balancing explicit in that rule.

The decision to allow the admission of the Section 510(k) evidence was a judgment call. Indeed, in making that determination, the district court recognized the limited probative value Section 510(k) evidence has in a products liability case. *Id.* at 1048 ("The 510(k) process may not speak directly to the applicable standard of care under Georgia law, but it does have probative value in the determination of this action."). And it further cited other authority which likewise noted that the Section 510(k) process "has minimal probative value" in a products liability case. *See Winebarger v. Boston Sci. Corp.*, No. 3:15CV211-RLV, 2015 WL 5567578 (W.D.N.C Sept. 22, 2015).

What makes the *In re Bard* decision most inapposite is that its ruling is premised on the fact that Georgia law does not hold "that only safety regulations" are relevant in design defect cases. 289 F. Supp. 3d at 1048 (discussing *Doyle v. Volkswagenwrk Aktiengesslschaft*, 481 S.E.2d 518 (Ga. 1997)). As discussed at length above, that is not the

law in Indiana, where a close connection between the relevant standard and safety is required. *Wade*, 966 N.E.2d at 194 ("[F]or evidence of compliance with governmental standards to be relevant, the standard itself must relate to the risk or product defect at issue[.]"); *see also* Ind. Code § 34-20-5-1.

When faced with a similar question as the one posed to the judge in *Bard,* I found that the Section 510(k) testimony would only confuse the jury and given the likelihood of confusion and extensive trial time necessary to explain the issues, any probative value was outweighed. [DE 407.] Defendants suggest my ruling had "no factual basis" because studies critical of Prolift (which triggered the FDA's post-clearance concerns resulting in Prolift being removed from the market) were not directly related to the Section 510(k) process. [DE 416 at 34-35.] But this framing of the issue ignores the additional basis for excluding the Section 510(k) evidence from trial under FRE 403: it was more prejudicial to ***both*** parties than probative to either. As explained, that evidence would not be probative of the key issue—*i.e.* safety. And allowing that evidence in, along with the rest of the FDA story, would likely have been even more harmful than beneficial to Ethicon. As I stated in my prior ruling:

> If the evidence regarding Prolift's §510(k) clearance had been admitted into evidence, almost assuredly, Prolift's whole FDA story would have been told to the jury, including evidence that after the Prolift device was marketed, it later received FDA scrutiny and was subsequently removed from the market after a series of exchanges with the FDA regarding its safety. This would require the introduction of additional evidence and testimony from regulatory experts and Ethicon employees. When balancing the probative value of the evidence against

> these dangers and the needless consumption of time, I find that excluding the evidence is appropriate.

[DE 407 at 8.]

As noted, it would not have been sensible, nor fair to the plaintiffs, to allow Ethicon to parade in a bunch of witnesses to talk about the FDA's Section 510(k) process and argue to the jury that this evidence shows how safe its product was, only to exclude the very prejudicial testimony about how the FDA strongly questioned the safety of the Prolift after the fact. What would have been sauce for the goose would have been sauce for the gander. I was not going to allow a one-sided presentation of Prolift's "FDA story." So I decided that the best approach was to exclude the FDA evidence altogether. This approach allowed the jury to focus on the critical issues in the case — was the product defective in its design and warnings? — without being distracted by the FDA side-show.

2. Lack of Curative Instruction after Plaintiffs' Closing Arguments

The next asserted error is that I did not issue a curative instruction after plaintiffs' rebuttal argument in which counsel rhetorically asked "Where is that industry standard?" that would justify or support Ethicon's decision to market Prolift without having conducted clinical trials in women prior to putting the product on the market. [DE 416 at 36.] Ethicon says that this was a misleading reference because plaintiffs' counsel knew there was an industry standard set by the FDA but that evidence had been excluded (as noted in the above section). In essence, Ethicon claims that it was precluded from telling the jury "the FDA didn't make us" do such testing.

Ethicon focuses on three specific statements made by plaintiffs' counsel during closing argument that Ethicon says caused great prejudice. They misleadingly suggest that all three were made during the "rebuttal closing argument." [DE 416 at 28.] In fact, two of the three offending statement were made during initial closing argument. [Trial Tr. 1653.] Ethicon concedes as much in its reply brief but nonetheless argues that "[r]egardless of when made, once the statements were made the only recourse was to grant a mistrial or provide a curative instruction[.]" [DE 422 at 13,n.5.] But the timing is important because there was no contemporaneous objection made to any of the statements, or attempt at a sidebar at the conclusion of plaintiffs' initial closing but prior to Ethicon's closing.

The Seventh Circuit has placed a high hurdle for Ethicon to clear in order to secure a new trial based on statements made during closing arguments. That is because "[c]losing arguments are the time in the trial process when counsel is given the opportunity to discuss more freely the weaknesses in his opponent's case and to highlight the strength of his own." *Jones v. Lincoln Elec. Co.*, 188 F.3d 709, 731 (7th Cir. 1999) "[I]mproper comments during closing argument rarely rise to the level of reversible error." *Probus v. K–Mart, Inc.,* 794 F.2d 1207, 1210 (7th Cir. 1986). "To warrant a new trial, '[s]tatements made during closing argument must be plainly unwarranted and clearly injurious to constitute reversible error.'" *Jones*, 188 F.3d at 730 (quoting *Gruca v. Alpha Therapeutic Corp.,* 51 F.3d 638, 644 (7th Cir. 1995)).

As noted above, Ethicon's counsel did not object during closing arguments. Instead, they waited until after all closing arguments concluded, including its own closing and plaintiffs' rebuttal had concluded. It was only then that they objected. And ***how*** they objected was a bit odd. No one from the defense team that was actually sitting at counsel's table lodged the objection. Instead, an attorney for Ethicon who was seated in the rear of the courtroom came rushing to the front of the courtroom with her arm in the air trying to get my attention. I was frankly taken aback by this. This occurred while I was in the process of telling the jury how I would go about reading the final instructions to them. *[See* Trial Tr. at 1737.] It seemed to me at the time that whatever the lawyer wanted to bring to my attention could wait and thus I instructed Ethicon's attorney to "please sit down" while I continued to address the jury. *Id*.

It is true, as Ethicon argues, that there may be valid strategic reasons not to object at "the very moment [opposing counsel] utters the comments at issue." *See United States v. Solis-Jordan*, No. 97 CR 814, 1999 WL 410038, at *6 (N.D. Ill. June 2, 1999) (cited by Ethicon). I'm not sure I see those concerns in this case. It would have been very simple for counsel who was seated at counsel table to simply ask if they could approach the bench just after the offending comments were made during the closing arguments. Indeed, defense counsel had no issue objecting contemporaneously during plaintiffs' closing at other times. [Trial Tr. 1646:25-1647:6.] Had defense counsel objected here, I would have allowed them to approach, and I could have dealt with the issue on the

spot during the argument if necessary. So there is no doubt Ethicon's counsel had ample opportunity to object before they actually did.

What's more, I think it was fair for me to expect that the Ethicon lawyer who would be lodging the objection would be the one who was actually doing the closing argument, not a lawyer seated in the back of the courtroom. Indeed, I made it clear to the parties prior to trial that I have a "one lawyer rule" that requires that objections be made by the lawyer responsible for that part of the trial whether it be the opening statements, the examination of witnesses or closing argument. That was especially important in this case where each side had at least a half-dozen lawyers assigned to it. It would have been a free for all to allow any lawyer to object at any time.

In sum, had defendants' counsel objected contemporaneously, or after plaintiffs' initial closing but before their own closing, and sought a sidebar to discuss their concerns, it may have been possible to address in a targeted fashion then and there, or to instruct plaintiffs' counsel not to make similar statements during rebuttal. But that did not happen and instead, defendants waited, and thus the only possible instruction to give would have come long after the offending statements were made, likely long after the jury had forgotten all about them.

Regardless, I am not convinced that any curative instruction would have been proper, let alone sufficiently necessary as to result in harm great enough to warrant a new trial in this case. I would have been required to explain to a jury, after the fact, the basis of my prior evidentiary rulings excluding Ethicon's proffered FDA-related

evidence. This would likely only confuse the jury, for the same reasons that such FDA-related evidence was excluded in the first place. Furthermore, this would have only served to highlight plaintiffs' counsel's errant statements during the closing, no doubt to Ethicon's detriment.

Defendants are somewhat misleading in implying that all FDA-related evidence would have been in their favor. As noted above, if I had allowed evidence of the FDA's Section 510(k) substantial equivalence process to come in, I would likewise have had to include the entirety of the proffered FDA evidence, including evidence of the FDA's later safety focused concerns and defendants' decision to withdraw Prolift from the market in response to those concerns. While I cannot know if the admission of this FDA evidence would have altered the jury's verdict, it was and remains my ruling that the evidence was not sufficiently relevant to the claims in this lawsuit to be deemed admissible.

Finally, it is hard to imagine that the few fleeting comments by plaintiffs' counsel made a difference in a complicated trial spanning two weeks time. Simply put, Ethicon has not met its burden under the demanding standard at play here. The motion for a new trial based on improper argument during closing must therefore be denied.

3. Testimony of Dr. Meng Chen Regarding TVT

Prior to trial, Ethicon sought to exclude certain documents authored by Ethicon Associate Medical Director Dr. Meng Chen, but did not seek to bar her testimony in full. [DE 234 at 19-20 (motion *in limine* to exclude "evidence or argument regarding post-sale

company documents authored by Dr. Meng Chen"); DE 279 (plaintiffs' motion to admit); DE 288 (defendants' opposition).] These documents related to "TVT", a vaginal mesh product sold by defendants prior to Prolift entering the market and which was made using the same polypropylene material as Prolift. At trial, Ethicon objected to deposition testimony from Dr. Chen because I limited defense counsel's cross-examination of plaintiffs' expert Dr. Elliott concerning TVT only to issues related to development of Prolift. [Trial Tr. 495:9-15 ("THE COURT: . . . I very specifically asked what the intention was as it relates to the TVT product, and the way it was pitched to me was: Well, it's very necessary to talk about the TVT in the development of a Prolift product, and that's what we're intending to talk about the TVT. This is getting beyond that.").]

I allowed Dr. Chen's testimony in a limited fashion because I found testimony concerning complications with TVT, a separate but similar device, was relevant to defendants' decisions to use polypropylene mesh material in Prolift as well. [Trial Tr. 1053:1-5 ("THE COURT: I do think that polypropylene and how it is made and the fact that it is used in the Prolift is relevant to this case; that it sort of sets the framework for the development of the sling, kind of led to the development of the Prolift.").] That is what Dr. Chen's testimony concerned. Ethicon offers nothing in the way of new argument on its belated objection to having Dr. Chen's testimony barred in full and I see no occasion to revisit my ruling or grant a new trial on this basis.

4. Failure to Warn and Causation Jury Instructions

Ethicon submits that two specific jury instructions contained misstatements of law which prejudiced it by either misleading or confusing the jury. Specifically, Ethicon claims that it was prejudicial error to exclude its proposed qualifier "not commonly known" in Instruction 20 as to Mrs. Kaiser's failure to warn claim, and in rejecting its additional instruction as to general and specific medical causation. [DE 416 at 40-41.] "To obtain a new trial based on incorrect jury instructions, [Ethicon] must establish that (1) the instructions did not accurately state the law, and (2) the error prejudiced [it] because the jury was likely to be misled or confused." *Johnson v. Gen. Bd. of Pension & Health Benefits of United Methodist Church*, 733 F.3d 722, 733 (7th Cir. 2013). This is a high bar to clear and Ethicon has not convinced me that the jury instructions contained any actual misstatements of law whatsoever, but instead continues to simply press its own linguistic preferences which deviate from the Indiana Model Instructions.

Ethicon asked for a jury instruction which would state that their duty to warn was limited to risks "not commonly known" to pelvic floor surgeons. Without this additional qualifier to Instruction 20, Ethicon argues this resulted in an improper jury instruction which misleadingly suggested there was "a duty to warn of all potential risks of Prolift." [DE 416 at 40.] Taken in isolation, that could possibly have been a colorable argument, but jury instructions cannot be read in isolation and instead should be considered "as a whole" to determine whether or not they contain misstatements of law which may have misled or confused the jury. *Johnson*, 733 F.3d at 732. The substance

of Ethicon's requested modification to Instruction 20 was already captured in Instruction 22, which explained that: "A medical device is 'unreasonably dangerous' if it exposes a patient to a risk of physical harm beyond that contemplated by an ordinary user of the product who uses the product with ordinary knowledge about the product's characteristics. An ordinary user of the product in this case is the community of pelvic floor surgeons." [DE 402 at 23.] This instruction, coupled with Instruction 20, made clear to the jury that they were to consider the knowledge of the community of pelvic floor surgeons in determining whether or not Ethicon adequately warned this defined group of "ordinary users" as to Prolift's risks. There was thus no misstatement of law and no error.

Ethicon next challenges the jury instructions as to causation, claiming that my exclusion of two if its proposed jury instructions on this issue meant that the jury instructions contained misstatements of law which likely misled the jury. Instruction 25, the causation instruction, from the Indiana Model Instructions stated that "A manufacturer's conduct is legally responsible for causing an injury if: (1) the injury would not have occurred without the conduct, and (2) the injury was a natural, probable, and foreseeable result of the conduct. This is called a "responsible cause." There can be more than one responsible cause for an injury." [DE 402 at 26.]

Ethicon claims that this instruction fails to sufficiently capture specific causation. But this instruction makes clear that a plaintiff must prove that "the injury would not have occurred without the conduct." *[Id.]* That ***is*** specific causation. Adding an

additional requirement that "a different warning would have changed the treating physician's treating decision," [DE 416 at 41], would have imposed an additional requirement that is not an element of causation under Indiana law. *See Lapsley,* 689 F.3d at 814; *see also Tucker v. SmithKline Beecham Corp.*, 701 F. Supp. 2d 1040, 1067 (S.D. Ind. 2010) (denying summary judgment on failure to warn because even if evidence was not "definitive either way" on causation, there was sufficient evidence to submit the claim to the jury because prescribing physician testified he would have "considered" a stronger warning in making any prescribing decision). Second, Ethicon claims there should have been an additional causation instruction as to "general causation" and "specific causation" to capture that Mrs. Kaiser was required to show both that Prolift was capable of causing her injuries and that Prolift did actually cause her injuries. In essence, Ethicon argues that it would have preferred more parsed language on causation, but does not actually make any showing as to how Instruction 25 contained an incorrect statement of law. Greater detail—which presumably Ethicon hoped would result in a jury being less likely to find Prolift was the cause of Mrs. Kaiser's injuries—may have been Ethicon's preference, but it was not required under Indiana law and the jury was sufficiently instructed as to what a plaintiff's burden is on matters of causation in a product liability suit.

In sum, Instruction 25 accurately stated Indiana law on causation and Ethicon's proposed additional parsing of this element would not have prevented juror confusion

but instead likely heightened it by implying elements and requirements which were not strictly elements of Mrs. Kaiser's claim.

E. Compensatory Damages

Having found that the jury's verdict in favor of Mrs. Kaiser was not irrational in and of itself, I must now consider whether that same evidence supports the amount of money the jury awarded Mrs. Kaiser. Ethicon challenges the jury's award of $10 million in compensatory damages, arguing that it is "grossly excessive" and unsupported by the evidence. [DE 416 at 42.]

As to compensatory damages "the jury's award may be vacated and a new trial granted only if the verdict is 'monstrously excessive' or if there is 'no rational connection between the evidence on damages and the verdict.'" *Inks v. Healthcare Distributors of Indiana, Inc.,* 901 F. Supp. 1403, 1409 (N.D. Ind. 1995) (quoting *McNabola v. Chicago Transit Authority,* 10 F.3d 501, 516 (7th Cir.1993)). "The verdict must stand unless there is no rational connection between the evidence and the jury's award." *Id.*

To determine whether this is the case, there are three key considerations: "(1) whether the award is 'monstrously excessive,' (2) whether there is no rational connection between the award and the evidence; and (3) whether the award is comparable to those in similar cases." *Marion County Coroner's Office v. EEOC*, 612 F.3d 924, 930-31 (7th Cir. 2010). "A monstrously excessive verdict is one that is 'a product of passion and prejudice.'" *Adams v. City of Chicago,* 798 F.3d 539, 543 (7th Cir. 2015) (quoting *Fleming v. Cnty. of Kane,* 898 F.2d 553, 561 (7th Cir. 1990)). "In order to

determine whether the jury's verdict was irrational, the district court must review the trial record as a whole in the light most favorable to the verdict. This perspective is essential, if we are to preserve the jury's role as the trier of fact." *Adams*, 798 F.3d at 543. The third factor helps guide the determination of whether the award is excessive, but one cannot simply extrapolate that an award is excessive if it is greater than an award in a prior comparable cases. "Awards in other cases provide a reference point that assists the court in assessing reasonableness; they do not establish a range beyond which awards are necessarily excessive." *Farfaras v. Citizens Bank & Tr. of Chicago,* 433 F.3d 558, 566–67 (7th Cir. 2006).

Mrs. Kaiser's injuries were non-economic in nature, consisting primarily of pain and suffering, and "these harms are difficult to monetize." *Maldonado v. Sinai Medical Grp., Inc.* 706 F. Supp.2d 882, 887 (N.D. Ill. 2010). Putting a number of long-term physical pain and suffering will never be an exact science. *Jutzi-Johnson v. United States*, 263 F.3d 753, 758 (7th Cir. 2001) ("The problem of figuring out how to value pain and suffering is acute, however. Various solutions, none wholly satisfactory, have been suggested . . ."). Nor can we expect a jury to apply some sort of methodical calculation to the award in part because "[j]uries do not explain their reasoning process." *Id.*

To be sure, there was persuasive evidence from both Mr. and Mrs. Kasier that the pain and agony that she experiences on a daily basis from the mesh that remains in her body to this day is both real and debilitating. She endured a second painful surgery in an effort to have the mesh removed, but much of it still remains. Mrs. Kaiser testified,

and her husband confirmed, that she lives in constant pain. For these injuries, the jury determined $10 million was appropriate. While an eight figure sum is a lot of money and larger than many other serious personal injury cases, it is not "monstrously excessive" compared to other vaginal mesh personal injury cases. Ethicon makes much of the fact that juries have awarded smaller amounts of damages in other Indiana cases involving physical injury, many of which involved catastrophic physical injury. [DE 416 at 44 (citing *Westray v.* Wright, 834 N.E. 2d 173 (Ind. Ct. App. 2005) and *Mitchell v. Baynes*, Monroe County Circuit Court (J. Verds. Repts Aug. 5, 2005).] Likewise, Ethicon points me to several Indiana cases where minor injuries resulted in awards which were reduced by the trial court. [*Id.* at 43.]

But I believe other vaginal mesh cases provide a more apt comparison, as this case is but one of tens of thousands of vaginal mesh cases that has been filed, many of which are still pending before the MDL Court in West Virginia. And many of these have been tried, resulting in verdicts of several million dollars. Indeed, a Pennsylvania appellate court recently affirmed a $5.5 million dollar compensatory (and $7 million punitive damage) award against Ethicon in a Prolift case. *Hammons v. Ethicon, Inc.*, 2018 PA Super 172, 2018 WL 3030754 (Pa. Super. Ct. June 19, 2018); *see also Gross v. Gynecare*, No. A-0011-14T2, 2016 WL 1192556, at *1 (N.J. Super. Ct. App. Div. Mar. 29, 2016) (affirming multimillion dollar award in Prolift case).

The fact the jury's award here is higher than in many of the Indiana cases cited by Ethicon, does not make this jury's compensatory damage award improper. "It is

entirely possible that another jury might have evaluated [Mrs. Kaiser's] damages more modestly, but that is not the standard." *Adams*, 798 F.3d at 543. "Awards in other cases provide a reference point that assists the court in assessing reasonableness; they do not establish a range beyond which awards are necessarily excessive." *Farfaras,* 433 F.3d at 566–67. I am aware of no principle of Indiana law that would otherwise limit Mrs. Kaiser's damages.

The final aspect of compensatory damages to address is whether a reduction in the award is proper given that the amount the jury awarded was actually more than Mrs. Kaiser's counsel had requested. This is a tougher call. During closing arguments, plaintiffs' counsel asked for between $7 million and $9 million. [Trial Tr. 1675:2-7.] On one hand, there is something seemingly excessive about awarding Mrs. Kaiser more than her attorneys requested. But on the other hand, awarding her approximately 10-25% more does not seem ***monstrously*** excessive, given that the jury clearly felt that Mrs. Kaiser's physical pain and suffering justified a large damage award. Given that the jury's award was only slightly larger than what plaintiffs' counsel requested on a percentage basis, I will not reduce the amount of compensatory damages. *See, e.g., Davis v. Bamford, Inc.,* No. 8:11CV69, 2012 WL 3583184, at *3 (D. Neb. Aug. 20, 2012) (finding $7 million personal injury award not excessive under Nebraska law even though greater than requested in plaintiffs' closing argument given extent of physical injuries); *see also Jutzi-Johnson*, 263 F.3d at 761 (reversing verdict in favor of plaintiff and noting impropriety of $1.6 million award when plaintiff requested only $300,000 to $600,000).

F. Punitive Damages

The next issue to consider is the award of punitive damages. Despite my reservations to the contrary, all parties agreed that the New Jersey Punitive Damages Act governed that discreet issue in this case. I raised the issue about the applicability of New Jersey punitive damages law at least twice prior to trial because I was a little mystified as to why New Jersey law would apply to a tort that took place in Indiana. But the parties insisted that they had come to an agreement that New Jersey law should apply to the punitive damages issue, and so I yielded.

There are two issues to be considered as it relates to punitive damages: first, was there sufficient evidence to support an award of punitive damages; and if so, should the amount be reduced? I will take those issues up next.

1. Was There Sufficient Evidence for Punitive Damages to be Awarded?

Under New Jersey law, punitive damages are allowed "if the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions." N.J. Stat. Ann. § 2A:15-5.12(a). Four factors apply: "(1) The likelihood, at the relevant time, that serious harm would arise from the defendant's conduct; (2) The defendant's awareness of reckless disregard of the likelihood that the serious harm at issue would arise from the defendant's conduct; (3) The conduct of the defendant upon learning that its initial conduct would likely cause

harm; and (4) The duration of the conduct or any concealment of it by the defendant." *Ceasar v. Flemington Car & Truck Country*, No. A-1464-12T3, 2014 WL 1613422, at *10–11 (N.J. Super. Ct. App. Div. Apr. 23, 2014).

"[C]ircumstances of aggravation and outrage, beyond the simple commission of a tort, are required for an award of punitive damages. In other words, mere negligence, however gross, is not enough." *Pavlova v. Mint Mgmt. Corp.*, 868 A.2d 322, 326 (N.J. Super. Ct. App. Div. 2005) (citation omitted). In the products liability arena, whether punitive damages are allowed "may turn on whether the manufacturer wantonly disregarded a high probability that injury would occur once the defect manifested itself in the situation that the plaintiff encountered." *Zakrocki v. Ford Motor Co.*, No. L-10179-02, 2009 WL 2243986, at *23 (N.J. Super. App. Div. July 29, 2009). Put another way, "where the manufacturer knew of the dangers created by its product and failed to warn users of serious health hazards," punitive damages may be allowed. *Gross v. Gynecare*, No. L-6966-10, 2016 WL 1192556, at *26 (N.J. Super. Ct. App. Div. 2016).

Ethicon raises various arguments in support of its position, namely that Prolift was a useful product, which met a real demand amongst surgeons, was an improvement over previously available vaginal meshes, and "underwent an extensive design, design validation, and design verification process." [DE 416 at 24-25.] This may all well be very true and Ethicon certainly submitted evidence in support this. But there was also evidence that Ethicon was aware of the dangers and problems associated with Prolift but chose to launch it any way, and that after further problems continued to arise

once on the market, Ethicon continued to market it as-is without disclosing these risks to surgeons.

For example, there was testimony that nearly a year before Prolift's launch, there were concerns about mesh shrinkage. [Trial Tr. 359:4-360:4; Ex. P0521.] At launch, Ethicon knew that Prolift's mesh would need to be replaced with a new type of mesh, but the product was marketed nonetheless. [Trial Tr. 364:2-22.] This was not disclosed to surgeons performing procedures with Prolift. [*Id.*] Indeed, in an internal Ethicon email from October 2008, years after Prolift was launched and approximately three months before Mrs. Kaiser had her surgery, refers to this problematic mesh material as the "best of a bad lot." [DE 395, Ex. A, Robinson Tr. 552:16-554:2.] And the IFU, the key place where risks related to Prolift should have been disclosed in order to apprise surgeons, failed to reference the known likely types of pain, including pain associated with intercourse as experienced by Mrs. Kaiser. [Trial Tr. 393:3-17, 397:1-12; DE 395, Ex. B Klinge Tr. 1018:2-24.] The jury was entitled to credit this evidence.

Lastly, it is worth noting that appellate courts in other states (applying New Jersey law of punitive damages) have affirmed substantial punitive damage awards on similar facts in Prolift vaginal mesh cases. *Gross*, 2016 WL 1192556, at *1 (affirming $7.76 punitive damage award in Prolift vaginal mesh case); *Hammons*, 2018 PA Super 172 (affirming $7 million punitive damage award in Prolift vaginal mesh case). While these decisions do not by any means dictate or control the outcome here, they mollify any notion that the jury here behaved irrationally or contrary to New Jersey law.

2. Should the Punitive Damage Award be Reduced?

The final issue to address is whether, having accepted that Mrs. Kaiser was entitled to punitive damages as a matter of law, a remittitur of the $25 million amount awarded is necessary. I have thus far found all of Ethicon's arguments unpersuasive and upheld the jury's verdict, but on this issue I must cut the other way. The amount of the jury's punitive damage award is not reasonable and justified in this case.

Independent review by the trial court of any punitive damage award is mandatory under New Jersey law. "Before entering judgment for an award of punitive damages, the trial judge ***shall*** ascertain that the award is reasonable in its amount and justified in the circumstances of the case, in light of the purpose to punish the defendant and to deter that defendant from repeating such conduct." N.J. Stat. Ann. § 2A:15-5.14(a) (emphasis added); *Inter Med. Supplies Ltd. v. EBI Med. Sys., Inc.*, 975 F. Supp. 681, 699 (D.N.J. 1997), *aff'd and remanded*, 181 F.3d 446 (3rd Cir. 1999) (holding that New Jersey Punitive Damages Act mandates "greater judicial scrutiny of jury awards than had existed under the common law"). The statute further empowers me to reduce or eliminate the award "[i]f necessary to satisfy the requirements" listed in the previous sentence. *Id.*

The New Jersey Punitive Damages Act further imposes a statutory cap on punitive damages. Under this law, punitive damages can be no more than five times the compensatory damages. N.J. Stat. Ann. § 2A:15–5.14(b). Of course, the jury's $25 million award is within this cap, representing "only" 2.5 times the jury's compensatory

damages award. But, as other courts applying New Jersey's punitive damages regime have noted, when considering multi-million dollar awards, "the ratio alone is of little assistance" because "one naturally expects a much lower ratio when a substantial award of compensatory damages has been made[.]" *Inter Med. Supplies,* 975 F. Supp. at 701.

There is also a constitutional component to my review of the punitive damages awarded. In that regard, when evaluating punitive damages awards, the Supreme Court has instructed me to consider three guideposts: "(1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 418 (2003) (citation omitted).

As discussed, there was evidence which tended to show Ethicon was well aware of known risks associated with Prolift and either recklessly or intentionally concealed those risks for years. The jury further heard many details of Mrs. Kaiser's physical pain and suffering which were the result of defendant's conduct. Furthermore, the jury heard evidence regarding defendants' net worth (both are multi-billion dollar corporations), but also heard evidence regarding defendants' actual profits made off of Prolift in Indiana. The punitive damages in this case were only to address them as to Indiana (as opposed to nationwide or in other states given the many other pending

lawsuits involving Prolift against defendants). *See Philip Morris USA v. Williams,* 549 U.S. 346, 353 (2007) (reiterating holding that states may not impose their policy preferences as to punitive damages on neighboring states). Importantly, defendants' profitability from Prolift was a little over $150,000 in Indiana. [Trial Tr. 1060:2.] This fact gives me pause and causes doubt as to the reasonableness of the punitive damage award in this case given that New Jersey law requires that "[t]he profitability of the misconduct of the defendant" to be an express consideration in determining the amount of punitive damages to award. N.J. Stat. Ann. § 2A:15-5.12(c)(2). Thus while "[a]n otherwise valid award of punitive damages will not be set aside unless 'manifestly outrageous' or 'clearly excessive,'" I believe this is such a case. *Smith v. Whitaker*, A.2d 243, 254 (N.J 1999) (citations omitted). That is because "an award of punitive damages does not logically depend on the extent of the injury sustained by an individual plaintiff. Rather, 'the amount of such an award is determined from the perspective of the defendant.'" *Id.* at 255 (citations omitted). Here, while the jury heard evidence and the parties stipulated to defendants' net worth being $70 billion, the award of $25 million represents over 166 times the amount of relevant profits earned by defendants which from the perspective of the defendant is clearly excessive.

Having determined that a remittitur is warranted, I must now determine a number. Admittedly, this remains an inexact science but there remains guidance as to what the punitive damages award should be. Here, the jury's $10 million compensatory award is sizable and larger than many other Prolift vaginal mesh verdicts. And "[w]hen

compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee." *Campbell,* 538 U.S. at 425. I believe this statement from the Supreme Court is applicable here, given the size of the compensatory damage award in this case. *See also Davids v. Novartis Pharm. Corp.*, 977 F. Supp. 2d 171, 184 (E.D.N.Y. 2013) (applying New Jersey Punitive Damages Act in products liability case) ("[G]iven the large compensatory damages awarded in this case, the Court finds that requires a further reduction in the punitive damages award from five times the compensatory damages to twice the compensatory damages[.]"); *Inter Med. Supplies,* 975 F. Supp. at 701 (remitting $106 million dollar punitive damage award to $50 million under New Jersey law when compensatory damages were approximately $48 million); *Ceasar*, 2014 WL 1613422, at *15 (affirming remittance of punitive damages to $3 million from $5.5 million when compensatory damages were $2 million).

Given the foregoing authority, I will remit the jury's original $25 million punitive damage award to a 1:1 ratio, or $10 million. This is a reasonable award, in line with both the Supreme Court's due process jurisprudence on punitive damages and the New Jersey Punitive Damages Act. And given that Ethicon's profits in Indiana were approximately $150,000, a $10 million award remains substantial, which serves New Jersey's Punitive Damages Act's goal of ensuring that "the wrongdoing does not become a cost of business for the defendant." *Tarr v. Bob Ciasulli's Mack Auto Mall, Inc.*, 943 A.2d 866, 872 (N.J. 2008); *Smith*, 734 A.2d at 255 ("[T]he amount awarded should be

sufficient to serve the purpose of deterring future misconduct by defendant."); *see also Inter Med. Supplies*, 975 F. Supp. at 700 (reducing punitive damage award from $106 million to $50 million where profits realized from wrongful conduct were estimated at $97 million).

Of course, I cannot within my constitutional powers simply reduce the amount of punitive damages that the jury awarded by fiat. *Hetzel v. Prince William Cty., Va.*, 523 U.S. 208, 211 (1998) ("[I]n accord with the Seventh Amendment's prohibition on the reexamination of facts determined by a jury, a court has no authority, upon a motion for a new trial, 'according to its own estimate of the amount of damages which the plaintiff ought to have recovered, to enter an absolute judgment for any other sum than that assessed by the jury.'") (quoting *Kennon v. Gilmer*, 131 U.S. 22, 29 (1889); Wright & Miller, Fed. Prac. & Proc. Civ. § 2815 (3d ed.); *Inter Med. Supplies*, 975 F. Supp. at 702 ("A district court that finds the amount of an award of damages to be excessive cannot merely order a reduction in the award. The court can, however, order a new trial limited to the issue of damages, or condition the denial of a new trial on plaintiff's acceptance of the reduced damage award.") (citations omitted). Instead, having found the amount of punitive damages awarded in this case excessive, I will conditionally grant Ethicon's motion for a new trial as to the amount of punitive damages, subject to Mrs. Kaiser not accepting of a reduced $10 million punitive damage award. That is, Mrs. Kaiser now faces a choice: she can either accept a reduced punitive damage award

(and thus be awarded $20 million dollars in total compared to the original $35 million awarded by the jury) or I will order a new trial on the issue of punitive damages.

Conclusion

Therefore, for the reasons stated above, the Court:

A. DENIES defendants Johnson & Johnson and Ethicon, Inc's motion for judgment notwithstanding the verdict; and

B. DENIES defendants Johnson & Johnson and Ethicon, Inc.'s motion for a new trial; and

C. DENIES defendants Johnson & Johnson and Ethicon, Inc.'s motion for remittitur of the jury's compensatory damage award; and

D. GRANTS defendants Johnson & Johnson and Ethicon, Inc.'s motion for remittitur of the jury's punitive damage award to $10 million.

Within 14 days, plaintiff shall inform defendants whether or not she will accept the remittitur and the parties will inform the Court within 21 days of their decision as to the remittitur of punitive damages.

SO ORDERED on August 8, 2018.

/s/ Philip P. Simon ___
PHILIP P. SIMON, JUDGE
UNITED STATES DISTRICT COURT